M2305M 4/13/99

Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES HFI-35

Food and Drug Administration
555 Winderley Place
Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-22

January 4, 1999

Sebastian D. Agliano, President
Agliano & Son Fish Co.
1821 E. 7th Ave.
Tampa, FL 33605

Dear Mr. Agliano:

On August 19, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 1821 E. 7th Ave., Tampa, FL. The investigator documented deviations from the Seafood HACCP Regulation in Title 21, Code of Federal Regulations, Part 123 (21CFR 123), causing the scombrotoxin forming species processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

> Failure to have and implement a written HACCP plan to control the potential histamine hazard that is reasonably likely to occur with the tuna and mahi mahi received, processed and distributed by your facility, in that your HACCP plan does not specify the "proper temperature" at receiving [21 CFR 123.6(b)]. In addition, although the hazard of histamine formation is reasonably likely to occur during storage, it is not listed as a critical control point.
>
> Failure to adequately monitor all of the sanitation controls required in 21 CFR 123.11(b), in that the sanitation control records for August 19, 1998 state the equipment and facilities are in good operating condition, but condensation was found to be dripping on product boxes in the cooler, and peeling paint was on the wall directly above fish cutting boards in the processing room. In addition, while the sanitation checklist includes monitoring of disposal areas and grounds to avoid pest problems, it does not indicate that the processing areas are monitored for the presence of pests.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates for export of any of the seafood products processed at your facility until your firm is fully in compliance with the Seafood HACCP regulation.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,

Douglas D. Tolen
Director
Florida District